UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,617	03/15/2001	Paul O. Sheppard	98-29D1	6610

7590 06/02/2003

Robyn Adams
Patent Department
ZymoGenetics, Inc.
1201 Eastlake Avenue East
Seattle, WA 98102

EXAMINER
KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/809,617	SHEPPARD ET AL.	
	Examiner	Art Unit	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8,9,11-13,15,18-23 and 29-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *11,12,18,19 and 36* (40) is/are allowed.

6)☒ Claim(s) *8,9,13,15,19-23,29-35 and 39-41* (37) is/are rejected.

7)☒ Claim(s) *38* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Application Status

1. In response to the previous Office action, a written restriction requirement (Paper No. 5, mailed on August 27, 2002), Applicants filed an election and amendment received on March 4, 2003 (Paper No. 7). Said amendment canceled Claim 28. Thus, Claims 8, 9, 11-13, 15, 18-23, and 29-41 are pending in the instant Office action.

Election

2. Applicant's election without traverse of Group I, Claims 8, 9, 11-13, 15, 18-23, and 29-41, in Paper No. 7 is acknowledged.

Claims 8, 9, 11-13, 15, 18-23, and 29-41 will be examined herein.

Priority

3. The instant application is granted the benefit of priority for the U.S. Provisional Application No. 60/092,371 filed on July 10, 1998 and U.S. non-Provisional Application No. 09/351,414 filed on July 9, 1999 (the divisional parent application) as requested in the declaration and/or the first lines of the specification and/or the transmittal sheet.

Information Disclosure Statement

4. The information disclosure statement filed on February 20, 2002 (Paper No. 4) has been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copy. The Examiner notes that the IDS was called a "supplemental" IDS; however, it is the only one with the file.

Drawings

5. The drawings have been approved by the Draftsmen and are, therefore, entered as formal drawings acceptable for publication upon the identification of allowable subject matter. The instant application was published, as originally filed, in USPAP 2002/0137178A1 on September 26, 2002.

Compliance with the Sequence Rules

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to **fully** comply with the requirements of 37 C.F.R. § 1.821 through 1.825; Applicants' attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990).

a) On page 90, line 15, a 6-mer polypeptide is disclosed without benefit of a SEQ ID NO. If the noted sequences are in the sequence listing as filed, Applicants must amend the specification to identify the sequences appropriately by SEQ ID NO. If the noted sequences are not in the sequence listing as filed, Applicants must provide (1) a substitute copy of the sequence listing in both computer readable form (CRF) and paper copy, (2) an amendment directing its entry into the specification, (3) a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. § 1.821 (e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d), and (4) any amendment to the specification to identify the sequences appropriately by SEQ ID NO.

Objections to the Specification

7. The specification is objected to because the title is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are drawn (see M.P.E.P. § 606.01). The Examiner suggests the following new title:

---Polynucleotides Encoding Disintegrin Homologs, Related Products and Methods---

8. In the specification, the Abstract is objected to for not completely describing the disclosed subject matter (see M.P.E.P. § 608.01(b)). It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its completeness is essential. The Examiner suggests the inclusion of the source species, human, for completeness. Correction is required.

9. The specification is objected to for inappropriate notation of an internet address. On the following pages, an internet address is cited in an unacceptable form. See M.P.E.P. § 707.05(e) for the acceptable notation of an internet address.

a) On page 85, line 11.
b) On page 93, line 28.
c) On page 94, lines 22-23.

Correction is required.

Claim Objections

10. Claims 30 and 31 are objected to under 37 C.F.R. § 1.75 as being a substantial duplicate of claims 29 and 9, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is

proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See M.P.E.P. § 706.03(k). By virtue of the encoding language in Claims 30 and 31, said claims are read as open, which is an identical interpretation to that of Claims 29 and 9, respectively. See rejection under 35 U.S.C. § 112, second paragraph below for appropriate closed language to obviate the instant objection.

11. Claims 37 and 39 are objected to for a typographical error. On line 2 of each claim, the first occurrence of "amino acid" must be followed by ---sequence--- as written in similar claims. Correction is required.

12. Claim 38 is objected to for depending from a rejected claim.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 8 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The scope of the instant claim is unclear. Residues at positions 443-445 of SEQ ID NO:2 are E-C-D. Can the claimed polynucleotide encode any contiguous 13 amino acids of SEQ ID NO:2 so long as an E-C-D sequence is encoded? For example, residues 393-395 are Glu-Cys-Asp in SEQ ID NO:2. It is unclear if the fragment must be around positions 443-445 or if any fragment encoding E-C-D within its sequence meets all the limitations of the claim. Clarification and/or amendment are required.

14. Claim 15 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the instant claim, the term "fusion protein" is particularly problematic due to the domain nature of the disclosure polypeptide. One of skill in the art could consider the "natural" fusion the protease domain and the integrin binding domain as a fusion protein. Must the first segment be heterologous to (not naturally associated with) the second segment? Clarification is required.

15. Claims 20-23 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 20, item b, more than one polynucleotide is encompassed in claim 12, thus, the DNA segment must comprise "**a** polynucleotide" (emphasis added) for proper and clear antecedent basis.

16. Claims 30 and 31 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 30 and 31 are unclear in scope, whether it is open or closed as to the encoding region. The Examiner suggests the following claim language to clarify a closed interpretation of the claim:

---30. An isolated polynucleotide that encodes a polypeptide, wherein the encoded polypeptide consists of residues 438-449 as shown in SEQ ID NO:2.---

Claim 31 can be similarly amended. Correction is required.

17. Claims 32 and 33 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitations implied by the term "immunogenic" are unclear. On page 69 of the instant specification, antigenic fragments of SEQ ID NO:2 are described specifically as having hydrophilic residues. Is hydrophilicity a requirement of the polypeptide encoded by the claimed polynucleotide? If so, which residues are considered hydrophilic; on page 31 of the specification, hydrophobic residues (not hydrophilic) are defined. And how many would be required to constitute a hydrophilic fragment? Clarification and/or amendment are required.

18. Claims 32 and 33 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "as shown in SEQ ID NO:2" is unclear considering that SEQ ID NO:2 is a 696 amino acid polypeptide and the noted fragments are 13 and 14 consecutive amino acids in Claims 32 and 33, respectively. Clarification and/or amendment are required.

19. Claim 41 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Item b is unclear reciting "**a** polynucleotide that is ___ complementary to a" (emphasis and blank added). The article "a" indicates that the polynucleotide is one of a group. Is the claimed polynucleotide ---fully complementary--- to SEQ ID NO:1? If so, only one

polynucleotide (clearly claimed as "**the** polynucleotide") is appropriate. Clarification and/or amendment are required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20. Claims 8, 15, 32, 34, 35, 37, and 39 are rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner notes that although the amendment was filed on the same day as the instant application, the declaration does NOT mention the inclusion of said amendment. Thus, the amendment cannot be considered "originally filed". Also the Examiner notes that the provisional application, 60/092,371, is not expressly incorporated by reference (only relied on for a priority date) and, thus, cannot be used as support for amendments.

The phrases considered new matter by the Examiner are cited below. Applicants must cite clear support (page and line number) for the amendments to the claims or must delete the new matter.

a) In Claim 8, "contiguous sequence of 13 amino acids" ...including "residues at positions 443-445 of SEQ ID NO:2". No mention of **13** contiguous residues is found anywhere in the specification. Mention of 14 contiguous residues is found as relating to the entirety of SEQ ID NO:2 (page 3) or residues 383-464 (page 5), but **not** particularly including **this fragment**.

b) In Claim 15, "contiguous sequence of 13 amino acids between residues 383 and 464 of SEQ ID NO:2". No mention of **13** contiguous residues is found anywhere in the specification.

c) In Claim 32, "13 consecutive amino acids as shown in SEQ ID NO:2". No mention of **13** contiguous or consecutive residues is found anywhere in the specification.

d) In Claim 34, "which has at least 90% identity to the amino acid sequence as shown in SEQ ID NO:2 from residue 383 to residue 464". The only mention of **90% identical** is related to polypeptides, specifically the entirety of SEQ ID NO:2 (see page 26). DNA encoding a polypeptide that is at least 80% identical to 383-464 is found on page 5.

e) In Claim 35, "which has at least 90% identity to the amino acid sequence as shown in SEQ ID NO:2 from residue 164 to residue 464". The only mention of **90% identical** is related to polypeptides, specifically the entirety of SEQ ID NO:2 (see page 26).

f) In Claim 37, "which has at least 90% identity to the amino acid sequence as shown in SEQ ID NO:2 from residue 164 to residue 696". The only mention of **90% identical** is related to polypeptides, specifically the entirety of SEQ ID NO:2 (see page 26).

g) In Claim 39, "which has at least 90% identity to the amino acid sequence as shown in SEQ ID NO:2 from residue 383 to residue 696". The only mention of **90% identical** is related to polypeptides, specifically the entirety of SEQ ID NO:2 (see page 26). DNA encoding a polypeptide that is at least 80% identical to 383-696 is found on page 5.

In light of these extensive new matter issues, the Examiner will set forth below the applied priority date for each of the pending claims as used herein to apply prior art and the reasons for said application.

8	March 15, 2001 (no support in parent or instant application)
9	July 9, 1999 (no support in provisional for 437-450 fragment)
11-13	July 10, 1998 (support in provisional)
15	March 15, 2001 (no support in parent or instant application)
18-23	July 10, 1998 (support in provisional for noted fragments)
29-31	July 9, 1999 (no support in provisional for 437-450 or 438-449 fragments)
32	March 15, 2001 (no support in parent or instant application)
33	July 9, 1999 (no support in provisional for encoding 14 consecutive residues of SEQ ID NO:2, although 14 consecutive base pairs of SEQ ID NO:1 is supported)
34-35	March 15, 2001 (no support in parent or instant application)
36	July 9, 1999 (no support in provisional for 164-464 fragment)
37	March 15, 2001 (no support in parent or instant application)
38	July 10, 1998 (support in provisional)
39	March 15, 2001 (no support in parent or instant application)
40	July 10, 1998 (support in provisional)
41	July 10, 1998 (support in provisional)

21. Claims 8, 15, and 29 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to polynucleotides encoding polypeptides with functional limitations (binds integrin), but limited structural limitations.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which

is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

In the instant specification, a polynucleotide encoding a multi-domain protein is described in the form of SEQ ID NO:1, which encodes SEQ ID NO:2, a 696 amino acid protein. The domains of this polypeptide are 1-163 (propeptide domain), 164-382 (protease domain), 383-464 (disintegrin domain which binds integrin), and 465-696 (cysteine-rich domain). In each of the instant claims, a *very* limited portion of the disintegrin domain is required along with the "binds an integrin" functionality. Such a limited portion cannot, itself, support the function. By virtue of the open claim language, **any** additional structure can be added to the limited portion of structure required by the claims to produce the claimed, functional polynucleotide. Without any correlation of how the structure of the single species disclosed (SEQ ID NO:2 from 383-464) performs the claimed function, one of skill in the art would be unable to recognize the structure of the other members of the claimed genus by virtue of the instant disclosure. Therefore, claims are not adequately described by the specification as originally filed.

22. Claims 9 and 30-33 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to

polynucleotides encoding polypeptides with no functional limitations, but limited structural limitations.

The Court of Appeals for the Federal Circuit has recently held as described above concerning written description.

In the instant specification, a polynucleotide encoding a multi-domain protein is described in the form of SEQ ID NO:1, which encodes SEQ ID NO:2, a 696 amino acid protein. The domains of this polypeptide are 1-163 (propeptide domain), 164-382 (protease domain), 383-464 (disintegrin domain which binds integrin), and 465-696 (cysteine-rich domain). In each of the instant claims, a *very* limited portion of the disintegrin domain is required with no required functionality. Such a limited portion cannot, itself, support an inherent function like the entire disintegrin domain would. By virtue of the open claim language, **any** additional structure can be added to the limited portion of structure required by the claims to produce the claimed polynucleotide. Without any correlation of how the structure of the single species disclosed (SEQ ID NO:2 from 383-464) performs a function, one of skill in the art would be unable to recognize the structure of the other members of the claimed genus by virtue of the instant disclosure. Therefore, claims are not adequately described by the specification as originally filed. Moreover, the genus of the instant claims also contains polynucleotides within the sequence fragment limitations, but having different function. Applicants have not fully described a genus that has sequence fragment limitations in the absence of functional limitations.

23. Claim 13 is rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. The instant claim is drawn to polynucleotides encoding polypeptides with limited structural limitations and no disclosed functional limitation.

The Court of Appeals for the Federal Circuit has recently held as described above concerning written description.

In the instant specification, a polynucleotide encoding a multi-domain protein is described in the form of SEQ ID NO:1, which encodes SEQ ID NO:2, a 696 amino acid protein. The domains of this polypeptide are 1-163 (propeptide domain), 164-382 (protease domain), 383-464 (disintegrin domain which binds integrin), and 465-696 (cysteine-rich domain). In the instant claim, the cysteine-rich domain is the only required structure; no function is found in the claim limitations. By virtue of the open claim language, **any** additional structure can be added to the limited portion of structure required by the claims to produce the claimed polynucleotide. It is impossible to correlate the structure of the single species disclosed (SEQ ID NO:2 from 465-696) to a function since none is described. Therefore, claims are not adequately described by the specification as originally filed.

24. Claim 13 is rejected under 35 U.S.C. § 112, first paragraph, enablement. Specifically, since the claimed invention is not supported by either an asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 U.S.C. § 101

35 U.S.C. § 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

25. Claim 13 is rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either an asserted utility or a well-established utility. Claim 13 is drawn to a domain of a disclosed integrin binding protein; said protein also contains a protease domain. However, the instant claim is limited to the cysteine-rich portion of the full-length protein. No asserted of this portion of the protein, in particular, is found in the specification and/or the art. For these reasons, the instant claim lacks a patentable utility.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

26. Claims 8, 15, 32, 34, 35, 37, 39 are rejected under 35 U.S.C. § 102(b) as being anticipated by Sagane *et al.* (Metalloproteinase-like, disintegrin-like, cysteine-rich proteins MDC2 and MDC3: novel human cellular disintegrins highly expressed in the brain. Biochem. J.

(August, 1998) 334:93-98). The instant claims are drawn to polynucleotides encoding the following polypeptides related to SEQ ID NO:2: (a) having at least 13 contiguous residues of sequence around positions 443-445 and 383-464 and (b) having at least 90% sequence identity to residues 383-464, 164-464, 164-696, and 383-696.

Sagane *et al.* teach a 3054 base pair polynucleotide that encodes MDC3. Said polynucleotide encodes residues 9-664 of SEQ ID NO:2 with two mismatches in the region between 164 and 382 (see attached alignments). While the C-terminus of SEQ ID NO:2 is not taught, claims drawn to polynucleotides encoding a polypeptide having at least 90% identity to SEQ ID NO:2 from 383-696 are anticipated because this region is 90% identical over its full-length, even considering the missing amino acids.

27. Claims 9, 29-31, 33 are rejected under 35 U.S.C. § 102(a) as being anticipated by Sagane *et al.* (see above). The instant claims are drawn to polynucleotides encoding the following polypeptides related to SEQ ID NO:2: (a) 437-450, (b) 438-449, and (c) having at least 14 consecutive amino acids.

Sagane *et al.* teach a 3054 base pair polynucleotide that encodes MDC3. Said polynucleotide encodes residues 9-664 of SEQ ID NO:2 with two mismatches in the region between 164 and 382 (see attached alignments).

28. Claims 8, 15, 32, 34, and 35 are rejected under 35 U.S.C. § 102(b) as being anticipated by Sagane (GenBank Accession Number AB009673. Mus musculus mRNA for ADAM23, complete cds. Published August 17, 1999). The instant claims are drawn to polynucleotides encoding the following polypeptides related to SEQ ID NO:2: (a) having at least 13 contiguous

residues of sequence comprising E-C-D (which is also found at positions 392-394) and 383-464 and (b) having at least 90% sequence identity to residues 383-464 and 164-464.

Sagane (GenBank AB009673) teaches a 2891 base pair polynucleotide that encodes a mouse ADAM23. Said polynucleotide encodes residues 9-664 of SEQ ID NO:2 with twenty mismatches (see attached alignment). The mismatches do not interrupt the contiguous or % identity requirements of the instant claims.

29. Claims 8, 32, 34 are rejected under 35 U.S.C. § 102(e) as being anticipated by Fanslow *et al.* (WO 01/62905). The instant claims are drawn to polynucleotides encoding the following polypeptides related to SEQ ID NO:2: (a) having at least 13 contiguous residues of sequence comprising E-C-D (which is found at positions 443-445) and (b) having at least 90% sequence identity to residues 383-464.

Fanslow *et al.* teach a 1668 base pair polynucleotide that matches SEQ ID NO:1 from 1146-1994 except for two mismatches; this includes the 382-464 residue region of SEQ ID NO:2 (see attached alignment).

Other Relevant Art

30. The following are cited for completeness of the record and are not used in rejections above that would be redundant:

a) JP 11-155574 (Koji S.), published June 15, 1999, teaches the same DNA as Sagane *et al.* used in art rejections above.
b) WO 99/41388 (Ceretti D.), published August 19, 1999 and having priority data as early as February 11, 1998, teaches the Sagane *et al.* sequence as well.
c) WO 01/74857 (Lopez-Otin *et al.*), published October 11, 2001 and having priority data as early as April 3, 2000, teaches the Sagane *et al.* sequence as well. This document was also published as USPAP 2002/0001840 on January 3, 2002.

d) USPAP 2002/0042368 (Fanslow *et al.*), published April 11, 2002 and having priority data as early as February 25, 2000, is the U.S. filing of WO 01/62905 used in a rejection above.

Conclusion

31. Claims 11, 12, 18, 19, and 36, 40 are allowed. Claim 38 is objected to. Claims 8, 9, 13, 15, 19-23, 29-35, and 39-41 are rejected for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK
May 29, 2003